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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,426	08/21/2003	Michael Seul	LEAPS-C11	8876
7590 04/21/2005				
DARBY & DARBY P.C.		EXAMINER		
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New York, NY 10022-7513				
		ART UNIT	PAPER NUMBER	
		1641		

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/645,426	Applicant(s) SEUL, MICHAEL	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-103 is/are pending in the application.
- 4a) Of the above claim(s) 91-103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 76-103 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/21/04 & 8/21/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 76-90, drawn to an array of particle-attached ligands, classified in class 424, subclass 1.49.
- II. Claims 91-103, drawn to a method of multiplexed assaying for analytes capable of binding to an array of ligands, classified in class 436, subclass 525.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced with another materially different product such as a matrix immobilized with different ligands, and a separate reagent comprising a label conjugated to a second ligand that binds to the analyte.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Eric Mirabel on March 29, 2005 a provisional election was made with traverse to prosecute the invention of group I, claims 76-90. Affirmation of this election must be made by applicant in replying to this Office action. Claims 91-103 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

The information disclosure statement filed on December 29, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it fails to provide any list of references. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 84 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84 is indefinite for reciting "capable of". It is unclear of how the chemical tag is modified for capable of being interrogated optically. It is also unclear for reciting "interrogated". It is unclear whether the chemical tag has an optical characteristic or not.

Claim 88 is also indefinite for reciting "the ligands are capable of hybridizing to analytes". "Hybridizing" is known for the binding between two nucleic acids or nucleotides. However, claim 88 refers to the hybridization of a ligand and an analyte which can include antibodies and antigens or other molecules such as biotins and streptavidins.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 76-81, 84-90 are rejected under 35 U.S.C. 102(e) as being anticipated by Gombinski (US 6,297,062).

Gombinski teaches a matrix of magnetic particles wherein each magnetic particle in the matrix is coupled to a specific species of a second member of the pair forming group present in a discrete location in the matrix, which is different than the location of the other magnetic particles. The second member is specific to the biological entities or ligand in the sample. A detectable label that specifically binds to the biological entity is added. The matrix can be a 96-dot arrangement corresponding to a pattern to the 96-pin device and 96-well format or a nitrocellulose sheet, a line, or a strip (see col. 5, lines 1-30; col. 12, lines 5-10; col. 15, lines 15-23). The particle-attached ligands encoded with a chemical or physical characteristic are equivalent to the magnetic particle-attached biological entities-label. Such magnetic particle-attached biological-label is attached to the substrate/matrix. The biological entities are proteins such as monoclonal antibodies or oligonucleotides such as RNA or DNA (see col. 3, line 64-col. 4, line 9). Pair forming group is two biological entities capable of affinity binding to each other. Examples are two complementary DNA sequences, antibody and antigen; streptavidin and biotin; etc. (see col. 4, lines 45-57). The labels are radioactive labels, fluorescent or chemiluminescent which is chemical tag and capable of interrogated optically. The particles are exposed to an aliquot of liquid containing an analyte. The ligands (DNA) are capable of hybridizing to analytes containing within the liquid volume. (see col. 13, lines 27-30). Regarding claim 89, Gombinski teaches that the matrix comprising several arrays. Gombinski also teaches that the particles are positioned randomly (see figure 1, col. 12, lines 15-31). Regarding claim 90, since it is a process within a product claim, the process limitation is not given any patentable weight because regardless of how the

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process is, the product is still the same. The process of making the product does not alter the composition of the product. Thus, Gombinski still applies to claim 90.

Regarding the limitation of claim 86 "wherein the particles are attached to the substrate by chemical bonding", since it is drawn to a step of how the composition is made, it is not given any patentable weight because regardless of how the particles are affixed to the substrate, the structure of the result composition is not altered by such step. The particles are still affixed to the substrate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinski (US 6,297,062) in view of Nacamulli et al. (US 5,527,710).

Gombinski has been discussed above.

However, Gombinski fails to teach that the substrate is an electrode.

Nacamulli teaches antigen coated magnetic particles (particle-attached ligands) are deposited uniformly onto the working electrode from a flow stream by placing the magnet directly below. Electrochemiluminescent labeled antibodies are added and the labeled antibodies to the antigens on the magnetic bead immobilized on the surface of the electrode. (see col. 3, lines 10-30).

It would have been obvious to one of ordinary skills in the art to use the electrode taught by Nacamulli as a substrate for use in the composition taught by Gombinski since both teaches that magnetic particles-attached ligands are immobilized to a substrate or an electrode and using chemiluminescent labels. Detection using an ECL label requires a substrate such as an electrode because electrical pulses are needed to apply in order to modulate the ECL output. The ECL signals are useful in monitoring the rates of binding between the proteins/reactants as well as detecting a low concentration of sample.

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinski (US 6,297,062) in view of Hugl et al. (US 5,194,393).

Gombinski has been discussed above.

However, Gombinski fails to teach that the substrate is a semiconductor.

Hugl teaches a biosensor comprising a solid support such as a semiconductor; a layer of Langmuir-blodgett film attached thereto; at least one fluorescent dye which is located on top of the LB film; a receptor molecule located in or on the topmost layer of the LB film. (see col. 2, line 50-col. 3, line 35).

It would have been obvious to one of ordinary skills in the art to use the semiconductor solid support as taught by Hugl in the composition taught by Gombinski since both teaches that receptors and label particles such as fluorescent are immobilized on the substrate/semiconductor. Using a semiconductor as a solid support, one can measure changes in the surface potential at the interface of the medium and the insulative layer. By providing for reagents or protocols involving the

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assay medium, which result in a change in surface potential in relation to the present and amount of a particular analyte, measurement of the capacitance or related electrical determination can be related to the presence or amount of analyte in the assay medium.

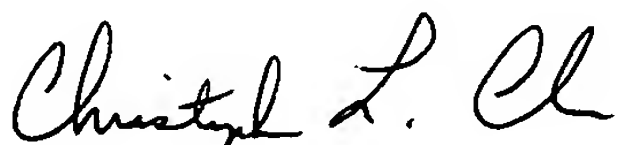
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
April 13, 2005


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641